

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN**

**KATHLEEN KRAUSE and ROLAND KRAUSE,
Plaintiffs,**

v.

Case No. 20-CV-104

**ETHICON INC and JOHNSON & JOHNSON,
Defendants.**

DECISION AND ORDER

Plaintiff Kathleen Krause alleges she suffers urinary incontinence and other injuries resulting from the implantation of a defective transvaginal polypropylene mesh device (“TVT”) manufactured by the defendants. She direct filed her case into an MDL in the Southern District of Virginia; after some discovery and motion practice, the case was remanded to this court. Prior to the remand, defendants filed a motion for partial summary judgment addressing the application of Wisconsin law to certain of plaintiffs’ claims. ECF # 31. Plaintiff filed a response. ECF # 33. Defendants do not appear to have filed a reply to plaintiff’s response; however, the parties agree that the motion is ready for decision. See ECF ## 56, 57. This decision and order resolves the motion.

I. FACTS

In April, 2004, Ms. Krause was implanted with a TVT. Dr. Anthony Hoang performed the procedure. Years later, Ms. Krause began experiencing incontinence, painful urination, and discomfort. In 2014, her physician noted that she suffered from cystitis, urge incontinence, and “erosion badly previous mesh sling.” ECF # 33-4.

At his deposition, Dr. Hoang testified that he began using TVT products to treat incontinence in 2001 or 2002. ECF # 33-5 at *4. Before he began using the TVT, he attended seminars about the product. *Id.* At the seminars, the TVT's Instructions For Use ("IFU") were discussed. *Id.* Dr. Hoang reviewed the IFU. *Id.* at *4-5. Dr. Hoang relied on the manufacturer to share all the risks it knew of in the IFU. *Id.* at 10.

Dr. Hoang discussed the risks associated with the TVT procedure before he performed the procedure on Ms. Krause. *Id.* at *6. At the time of the procedure, there was a known risk of erosion where the mesh would erode through the vaginal mucosa, but the rate was considered low. *Id.* at *9. However, at the time of the procedure, Dr. Hoang did not know that the TVT could cause an adverse foreign body reaction. *Id.*

Plaintiff retained Dr. Michael Margolis, a board certified expert in obstetrics and gynecology. He explained in his report that TVT implants are associated with serious complications, which are caused by factors including that the TVT mesh causes a chronic foreign body response. ECF # 33-6 at 8. Margolis further opined that the IFU in place at the time of Krause's surgery did not disclose all the risks associated with TVT, and understated the seriousness of the complications a patient might experience. *Id.* at 11-12. Margolis testified that Hoang was not able to pass along this information to Krause because the information was not in the IFU. *Id.* at 12.

II. LEGAL STANDARD

Summary judgment is required where "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). When considering a motion for summary judgment, I view the evidence in the light

most favorable to the non-moving party and must grant the motion if no reasonable juror could find for that party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 255 (1986).

III. DISCUSSION

The parties agree that three counts are contested under Ethicon's motion for summary judgment: common law fraud; negligent misrepresentation; and loss of consortium. ECF # 57 at 3. Plaintiff has asserted certain other claims, including negligence and strict liability failure to warn, which are not subject to the present motion.

Defendants first argue that the claims for fraud and negligent misrepresentation should be dismissed because they, like the unchallenged failure to warn claim, are subject to the learned intermediary doctrine, and are therefore duplicative of the failure to warn claim. Defendants do not explain their assertion that plaintiff's fraud and negligent misrepresentation claims are duplicative of her failure to warn claims. They provide no discussion of the elements of fraud, negligent misrepresentation, or failure to warn under Wisconsin law; nor do they discuss the facts plaintiff would rely on to establish any of these claims. Thus, I have no basis to conclude that the challenged claims are duplicative, regardless whether the learned intermediary doctrine applies. I will not dismiss these claims on the stated grounds, and I leave unresolved the question whether the learned intermediary doctrine applies.

Defendants next argue that they are entitled to summary judgment on the fraud claim because plaintiff cannot establish that Ethicon made any representation upon which she relied. Under Wisconsin law, to prove a claim of fraudulent misrepresentation by concealment and omission, a plaintiff must establish (1) defendant's failure to disclose a material fact; (2) defendant's intent to defraud; and (3) plaintiff's reliance on defendant's

disclosures. *Staudt v. Artifex Ltd.*, 16 F. Supp. 2d 1023, 1031 (E.D. Wis. 1998) (citing *Goerke v. Vojvodich*, 67 Wis.2d 102, 226 N.W.2d 211 (1975); *Ollerman v. O'Rourke Co., Inc.*, 94 Wis.2d 17, 26 & 43 n.26, 288 N.W.2d 95 (1980)); *Forst v. Smithkline Beecham Corp.*, 602 F.Supp.2d 960, 971 (E.D.Wis. 2009); *Tzakis v. Wright Medical Technology, Inc.*, 2020 WL 955016 (E.D. Wis. Feb. 27, 2020). Civil liability for misrepresentation exists when it is “foreseeable and intended that a fraudulent misrepresentation will be repeated to third parties and acted upon by them.” *Forst*, 602 F.Supp.2d at 971. Here, plaintiff’s expert has testified that Ethicon knew of various risks associated with the TVT but did not disclose those risks in the IFU. Compare *Tzakis*, 2020 WL 955016 at *3 (plaintiff adequately pled nondisclosure of material fact when he alleged that defendant distributed marketing and promotional materials that omitted information that the subject medical device had a high propensity for corrosion, fretting and fatigue and had a high rate of failures requiring corrective surgery). Plaintiff’s implanting doctor testified that he relied on the information in the IFU when discussing the risks of the TVT with plaintiff, and plaintiff’s expert has testified that doctors typically rely on the IFU in this way. This evidence is sufficient for a reasonable jury to find that defendants made a material misrepresentation upon which plaintiff, via her doctor, relied; therefore, I won’t grant summary judgment to defendants on these grounds.

Finally, defendants seek summary judgment on plaintiffs’ claim for loss of consortium claim on grounds that Ms. Krause testified at her deposition that she and her husband have not attempted sexual intercourse since she had her mesh implant, and that she has taken good care of her husband in the time since the implant. Under Wisconsin law, “a party may recover for loss of companionship of a spouse, which includes

intangibles such as love, affection, sex and solace.” *Estate of Ziolkowski v. WMK, LLC*, 378 Wis.2d 326, ¶ 73 (Wis.App. 2017). I agree with defendants that plaintiff has presented no evidence of such loss. She testified that she stopped having sex with her husband before the device was implanted. Plaintiff points to testimony that she and her husband went to Florida each year until 2016, when they stopped because of her husband’s Alzheimer’s disease. Plaintiff does not explain how this testimony is probative of a loss of “intangibles” such as love, affection or solace. I will grant summary judgment to defendants on the loss of consortium claim.

IV. CONCLUSION

For the foregoing reasons, **IT IS ORDERED** that defendants’ motion for partial summary judgment is **DENIED** with respect to the fraud and negligent misrepresentation claims, and **GRANTED** with respect to the loss of consortium claim.

Dated at Milwaukee, Wisconsin this 11th day of March, 2020.

s/Lynn Adelman _____
LYNN ADELMAN
U.S. District Judge